



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 06, 2002

Bruce N. Kuhlik
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, DC 20004

Dear Mr. Kuhlik:

Your petition, submitted on behalf of Hoffmann-La Roche Inc., requesting the Food and Drug Administration to refrain from approving ANDAs for isotretinoin drug products until adequate procedures and standards have been developed, was received by this office on 02/06/02. It was assigned docket number 02P-0059/CP 1 and it was filed on 02/06/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler
Dockets Management Branch

02P-0059

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